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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/790,651	03/01/2004	James F. Zucherman	5910-168	9758

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EXAMINER	
CUMBERLEDGE, JERRY L	
ART UNIT	PAPER NUMBER
3733	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/790,651	ZUCHERMAN ET AL.	
	Examiner	Art Unit	
	JERRY CUMBERLEDGE	3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-47 are rejected under 35 U.S.C. 102(e) as being anticipated by Brumfield et al. (US Pat. 5,562,662).

Brumfield et al. disclose a method for lateral insertion of an interspinous process implant comprising the steps of: accessing an upper and a lower spinous process laterally (Fig. 2)(column 5, lines 51-55) (column 9, lines 50-53); inserting the interspinous process implant (Fig. 2, ref. 20) between the spinous processes from a first lateral side of the spinous processes (Fig. 2)(column 9, lines 55-57, since in passing through the bores in ref. 29, it must pass from one side to the other side) and causing the interspinous process implant inserted by the inserting step to deploy adjacent a second lateral side of at least one of the upper and lower spinous processes (column 10, lines 3-14). The definition of "deploy" according to the Merriam-Webster Online Dictionary is "to spread out, utilize, or arrange for a deliberate purpose." The device of Brumfield et al. can be considered to be deployed, since it is being utilized and arranged for a deliberate purpose (i.e. to draw the rods 21 together, column 10, lines 10-14) and is adjacent to the spinal processes on both sides (Fig. 2). The method further comprises

a step of distracting the spinous processes apart, since, as seen in Fig. 12, ref. 137 is placed in between ref. 142 and V1, which would necessarily distract the components (e.g. the spinous processes on adjacent vertebrae) that are adjacent to ref. 137, and the distracting step and the inserting step are done in any order. The method further comprises a step of distracting the spinous processes apart, where the distracting step and the inserting step are done simultaneously, since the step of inserting can be considered to include inserting refs. 137 into position as shown in Fig. 12. The insertion step causes a wing (Fig. 3C, ref. 27) to be positioned adjacent to the first lateral side of at least one of the spinous processes (Fig. 2, since refs. 27 are on both lateral sides). The causing step causes a wing (Fig. 3C, ref. 27) to be deployed adjacent to the second lateral side (Fig. 2, since refs. 27 are on both lateral sides) of at least one of the spinous processes. The insertion step causes a first wing (Fig. 3C, ref. 27) to be positioned adjacent to the first lateral side of at least one of the spinous processes (Fig. 2, since refs. 27 are on both lateral sides) and the causing step causes a second wing (Fig. 3C, ref. 27) to be deployed adjacent to at least one of the second lateral sides of the spinous processes (Fig. 2, since refs. 27 are on both lateral sides).

Brumfield et al. disclose a method for lateral insertion of an interspinous process implant comprising the steps of accessing the spinous processes laterally (Fig. 2)(column 5, lines 51-55) (column 9, lines 50-53); inserting the interspinous process implant (Fig. 2, ref. 20) between the spinous processes from a first lateral side of the spinous processes (Fig. 2)(column 9, lines 55-57, since in passing through the bores in ref. 29, it must pass from one side to the other side); urging the interspinous process

implant through to the second lateral side of the spinous processes (Fig. 2)[column 9, lines 55-57, since in passing through the bores in ref. 29, it must pass from one side to the other side, and must be pushed (e.g. urged) into position]; and causing the interspinous process implant inserted by the inserting step to deploy so that a member of the interspinous process implant projects outwardly from a body of the interspinous process implant adjacent a second lateral side of at least one of the spinous processes (Fig. 2)(column 10, lines 3-14). The definition of "deploy" according to the Merriam-Webster Online Dictionary is "to spread out, utilize, or arrange for a deliberate purpose." The device of Brumfield et al. can be considered to be deployed, since it is being utilized and arranged for a deliberate purpose (i.e. to draw the rods 21 together, column 10, lines 10-14) and is adjacent to the spinal processes on both sides (Fig. 2). Regarding the "body," reference 38 can be considered to be the body and regarding the outwardly projecting member, reference 21 can be considered to be this portion.

Brumfield et al. disclose a method for lateral insertion of an interspinous process implant comprising the steps of: accessing the spinous processes laterally (Fig. 2)(column 5, lines 51-55) (column 9, lines 50-53); inserting the interspinous process implant (Fig. 2, ref. 20) between the spinous processes from a first lateral side of the spinous processes (Fig. 2)(column 9, lines 55-57, since in passing through the bores in ref. 29, it must pass from one side to the other side); and positioning the interspinous process implant inserted in the inserting step (column 10, lines 10-14), where the interspinous process implant extends from a second lateral side (Fig. 2, since it extends along both lateral sides). The method further comprises a step of distracting the spinous

processes apart, since, as seen in Fig. 12, ref. 137 is placed in between ref. 142 and V1, which would necessarily distract the components (e.g. the spinous processes on adjacent vertebrae) that are adjacent to ref. 137, and the distracting step and the inserting step are done in any order. The method further comprises a step of distracting the spinous processes apart, where the distracting step and the inserting step are done simultaneously, since the step of inserting can be considered to include inserting refs. 137 into position as shown in Fig. 12. The insertion step places an interspinous process implant member (Fig. 2, ref. 38) adjacent to the first lateral side of at least one of the spinous processes. The interspinous process implant member is selected from a wing, an arm, a leg (Fig. 2, ref. 38), and a hook. The positioning step places an interspinous process implant member (Fig. 2, ref. 38) adjacent to the second lateral side of at least one of the spinous processes (Fig. 2). The interspinous process implant member is selected from a wing, an arm, a leg (Fig. 2, ref. 38), and a hook.

Brumfield et al. disclose a method for the lateral insertion of an interspinous process implant, where the steps of inserting the interspinous process implant comprise: accessing the spinous processes laterally (Fig. 2)(column 5, lines 51-55) (column 9, lines 50-53); inserting the interspinous process implant (Fig. 2, ref. 20) laterally between the spinous processes (Fig. 2, near ref. 38), said interspinous process implant comprising a body (Fig. 2, refs. 21 and 38) having a deployable interspinous process implant member (Fig. 2, ref. 38 and ref. 21 on one side of processes); and deploying the implant member (column 10, lines 3-14), where the implant member extends from a second lateral side of the spinous processes. The method further

comprises a step of distracting the spinous processes apart, since, as seen in Fig. 12, ref. 137 is placed in between ref. 142 and V1, which would necessarily distract the components (e.g. the spinous processes on adjacent vertebrae) that are adjacent to ref. 137, and the distracting step and the inserting step are done in any order. The method further comprises a step of distracting the spinous processes apart, where the distracting step and the inserting step are done simultaneously, since the step of inserting can be considered to include inserting refs. 137 into position as shown in Fig. 12. The insertion step places an interspinous process implant member (Fig. 2, ref. 38 and ref. 21 on one side of processes) adjacent to the first lateral side of at least one of the spinous processes (Flg. 2). The interspinous process implant member is selected from a wing, an arm, a leg (Fig. 2, ref. 38 and ref. 21 on one side of processes), and a hook. The deploying step places an interspinous process implant member (Fig. 2, ref. 38 and ref. 21 on one side of processes) adjacent to the second lateral side of at least one of the spinous processes (Fig. 2). The interspinous process implant member is selected from a wing, an arm, a leg (Fig. 2, ref. 38 and ref. 21 on one side of processes), and a hook. The step of inserting further comprises using at least one tool (column 9, lines 65-67, i.e. driving tool) for lateral insertion of the interspinous process implant (Fig. 2).

Brumfield et al. disclose a method for the lateral insertion of an interspinous process implant, where the steps of inserting the interspinous process implant comprise: accessing the spinous processes laterally (Fig. 2)(column 5, lines 51-55) (column 9, lines 50-53); and inserting the interspinous process implant (Fig. 2, ref. 20)

laterally between said spinous processes (Fig. 2, near ref. 38), said interspinous process implant comprising: a body (Fig. 2, refs. 21 and 38) adapted to be placed between spinous processes (Fig. 2, ref. 38), where the body has a proximal end (Fig. 2, end near ref. 38) and a distal end (Fig. 2, end opposite proximal end); and a distraction guide (Fig. 2, ref. 25) extending from the distal end of the body. The method further comprises a step of distracting the spinous processes apart, since, as seen in Fig. 12, ref. 137 is placed in between ref. 142 and V1, which would necessarily distract the components (e.g. the spinous processes on adjacent vertebrae) that are adjacent to ref. 137, and the distracting step and the inserting step are done in any order. The method further comprises a step of distracting the spinous processes apart, where the distracting step and the inserting step are done simultaneously, since the step of inserting can be considered to include inserting refs. 137 into position as shown in Fig. 12. The step of inserting further comprises using at least one tool (column 9, lines 65-67, i.e. driving tool) for lateral insertion of the interspinous process implant (Fig. 2). The interspinous process implant further comprises at least one wing (Fig. 2, any of refs. 25).

Brumfield et al. disclose a method for the lateral insertion of an interspinous process implant, where the steps of inserting the interspinous process implant comprise: accessing the spinous processes laterally (Fig. 2)(column 5, lines 51-55) (column 9, lines 50-53); and inserting the interspinous process implant laterally between said spinous processes (Fig. 2, portion near ref. 38), said interspinous process implant comprising: a central body (Fig. 2, refs. 21 and 38) with a proximal end (Fig. 2, end near

ref. 38) and a distal end (Fig. 2, end opposite proximal end) , said central body having a longitudinal axis (along the length of the body); a sleeve (Fig. 12, refs. 115, 137 and 135) associated with the central body (Fig. 12), where the sleeve is adapted to be placed between spinous processes; and a distraction guide (Fig. 2, ref. 25) extending from the distal end of the central body (Fig. 2). The method further comprises a step of distracting the spinous processes apart, since, as seen in Fig. 12, ref. 137 is placed in between ref. 142 and V1, which would necessarily distract the components (e.g. the spinous processes on adjacent vertebrae) that are adjacent to ref. 137, and the distracting step and the inserting step are done in any order. The method further comprises a step of distracting the spinous processes apart, where the distracting step and the inserting step are done simultaneously, since the step of inserting can be considered to include inserting refs. 137 into position as shown in Fig. 12. The step of inserting further comprises using at least one tool (column 9, lines 65-67, i.e. driving tool) for lateral insertion of the interspinous process implant (Fig. 2). The interspinous process implant further comprises at least one wing (Fig. 2, any of refs. 25).

Brumfield et al. disclose a method for the lateral insertion of an interspinous process implant, where the steps of inserting the interspinous process implant comprise: accessing the spinous processes laterally (Fig. 2)(column 5, lines 51-55) (column 9, lines 50-53); and inserting the interspinous process implant (Fig. 2, ref. 20) laterally between said spinous processes (Fig. 2, portion near ref. 38), said interspinous process implant comprising: a central body (Fig. 2, refs. 21 and 38) with a proximal end (Fig. 2, end near ref. 38) and a distal end (Fig. 2, end opposite proximal end), said

central body having a longitudinal axis (the axis along the length of the device); a wing (Fig. 2, ref. 25) located at the proximal end of the central body; a sleeve (Fig. 12, ref. 115) associated with the central body, where the sleeve is adapted to be placed between spinous processes; and a distraction guide (Fig. 2, ref. 25) extending from the distal end of the central body. The method further comprises a step of distracting the spinous processes apart, since, as seen in Fig. 12, ref. 137 is placed in between ref. 142 and V1, which would necessarily distract the components (e.g. the spinous processes on adjacent vertebrae) that are adjacent to ref. 137, and the distracting step and the inserting step are done in any order. The method further comprises a step of distracting the spinous processes apart, where the distracting step and the inserting step are done simultaneously, since the step of inserting can be considered to include inserting refs. 137 into position as shown in Fig. 12. The step of inserting further comprises using at least one tool (column 9, lines 65-67, i.e. driving tool) for lateral insertion of the interspinous process implant (Fig. 2). The interspinous process implant further comprises a second wing (Fig. 12, ref. 25) located near the distal end of the central body.

Brumfield et al. disclose a method for the lateral insertion of an interspinous process implant, where the steps of inserting the interspinous process implant comprise: accessing the spinous processes laterally (Fig. 2)(column 5, lines 51-55) (column 9, lines 50-53); and inserting the interspinous process implant laterally between said spinous processes (Fig. 2, portion near ref. 38), said interspinous process implant comprising: a body (Fig. 2, refs. 21 and 38) adapted to be placed between spinous

processes, the body having a proximal end (Fig. 2, end closer to ref. 38) defining a first saddle (Fig. 2, ref. 28, top right), and a distal end (Fig. 2, end further from ref. 38) defining a second saddle (Fig. 2, ref. 28, top left); and the first saddle and the second saddle are adapted to receive adjacent spinous processes. The method further comprises a step of distracting the spinous processes apart, since, as seen in Fig. 12, ref. 137 is placed in between ref. 142 and V1, which would necessarily distract the components (e.g. the spinous processes on adjacent vertebrae) that are adjacent to ref. 137, and the distracting step and the inserting step are done in any order. The method further comprises a step of distracting the spinous processes apart, where the distracting step and the inserting step are done simultaneously, since the step of inserting can be considered to include inserting refs. 137 into position as shown in Fig. 12. After the insertion step the method further comprises a step of positioning the interspinous process implant (column 10, lines 10-14) between the spinous processes (Fig. 2, near ref. 38). The interspinous process implant further comprises positioning means (Fig. 2, refs. 25), where the positioning means retain the interspinous process implant between the spinous processes to limit extension and allow flexion. The positioning means is a tether (Fig. 2, refs. 25). The positioning means is a pin (Fig. 2, refs. 25). The positioning means is at least one arm extending from the proximal end and distal end of the interspinous process implant (Fig. 2, refs. 25). The positioning means further comprises a tether (Fig. 2, refs. 25). The step of inserting further comprises using at least one tool (column 9, lines 65-67, i.e. driving tool) for lateral insertion of the interspinous process implant.

Claims 1 and 48-50 are rejected under 35 U.S.C. 102(e) as being anticipated by Samani (US Pat. 5,645,599).

Samani discloses a method for lateral insertion of an interspinous process implant comprising the steps of: accessing an upper and a lower spinous process laterally (Fig. 3); b. inserting the interspinous process implant between the upper and the lower spinous processes from a first lateral side of the spinous processes (Fig. 3); and causing the interspinous process implant inserted by the inserting step to deploy adjacent a second lateral side of at least one of the upper and the lower spinous processes (Fig. 3)(Fig. 5). During insertion, the interspinous process implant has a small profile insertion configuration, and causing the implant to deploy causes the implant to assume an expanded projected configuration with at least one member of the implant projecting outwardly from a body of the implant and adjacent the second side of at least one of the upper and lower spinous processes so as to help maintain a position of the implant between the upper and lower spinous processes (column 4, lines 44-51, since inserting ref. 15 will cause the implant to expand outwardly). The deployed interspinous process implant contacts at least one of the upper and the lower spinous process (Fig. 3). The deployed interspinous process implant contacts a lateral side of at least one of the upper and the lower spinous processes (Fig. 3).

Response to Arguments

Applicant's arguments filed 07/18/2007 have been fully considered but they are not persuasive.

With regard to Applicant's argument that Brumfeld does not disclose an interspinous process implant that deploys adjacent to a spinous process, the examiner respectfully disagrees. The device comprises a portion that is between spinous processes (Fig. 2, ref. 38), and the portion is deployed, since the definition of "deploy" according to the Merriam-Webster Online Dictionary is "to spread out, utilize, or arrange for a deliberate purpose." The portion of Brumfield et al. can be considered to be deployed, since it is being utilized and arranged for a deliberate purpose (i.e. to draw the rods 21 together, column 10, lines 10-14) and is adjacent to the spinal processes on both sides (Fig. 2).

With regard to Applicant's argument that the Brumfeld device does not deploy adjacent to a lateral side of a spinous process since the device gives a wide berth surrounding all sides of the spinous processes, the examiner respectfully disagrees. The term "adjacent" requires relatively close position. *Ex parte Hadsel (PO BdApp) 109 USPQ 509*. The device is in relatively close position to the spinous processes (Fig. 2).

With regard to Applicant's argument that Brumfeld does not disclose a step of distracting apart spinous processes, the examiner respectfully disagrees. As the hook portions attach to the laminae they will distract the vertebrae from each other and since the spinous processes are attached to vertebrae, the spinous processes will in turn be distracted from each other. Fig. 12 which Applicant relies on shows that the vertebrae are further apart from each other than normal (i.e. the facet joints are not engaging one

another) and the spinous processes are in turn further apart from each other when compared to the natural state of the vertebrae (i.e. distracted).

With regard to Applicant's argument that Brumfeld does not disclose a distraction guide, the examiner respectfully disagrees. Initally, the device is distracting, as discussed above. Secondly, Applicant argues that the distractor does not contact the spinous processes at all, however this step is not being recited in claims 23, 28 and 33.

With regard to Applicant's argument that Brumfeld does not disclose two saddles adapted to receive spinous processes, the examiner notes that it has been held that the recitation that an element is "adapted to" perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. In re Hutchison, 69 USPQ 138. The saddles which the examiner refers to (Fig. 2, ref. 28, top right) (Fig. 2, ref. 28, top left) are capable of receiving spinous processes, since they are hooked shaped and can hook on to the spinous processes.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JERRY CUMBERLEDGE whose telephone number is (571)272-2289. The examiner can normally be reached on Monday - Friday, 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. C./
Examiner, Art Unit 3733
/Eduardo C. Robert/
Supervisory Patent Examiner, Art Unit 3733